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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,466	03/02/2000	James L. Hartley	0942.4680003/RWE/BJD	4289

26111 7590 02/17/2004

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/517,466	HARTLEY ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *3-9,12-14,17,22-25,30,31 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,10,11,15,16,18-21,26-29,32-34 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0101,0401,0603a,0603b*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I and of nucleic acids comprising attB1 nucleotide sequences in the reply filed June 27, 2002 is acknowledged. It is noted that while Applicant has identified claim 17 as reading on the elected invention, claim 17 is clearly drawn to a molecule comprising an "attB2 nucleotide sequence," and accordingly claim 17 has been withdrawn. It is further noted that Applicant did not specify which of the vectors of claim 33 encompass attB1 sequences. Upon reviewing the specification, the examiner has determined that the following vectors include attB1 sequences: pMAB58, pMAB62, pMAB85, and pMAB86. If additional vectors are in fact encompassed by the elected invention, Applicant is requested to identify those vectors in the response to this Office action.

2. Applicant's election with traverse of molecules comprising "one or more transcriptional regulatory sequences" in the reply of June 27, 2002 is also acknowledged. The traversal is on the ground(s) that "a reasonable number of species may be claimed," that the elements recited in claims 10-14 are "closely related subject matter," and that a search of all species would not pose a serious burden. This is not found persuasive for the following reasons. The inclusion of each of the different types of "functional or structural nucleotide sequences" recited in claims 10-14 in a nucleic acid molecule would result in molecules that are distinct from one another both in their sequence/structure and in their functional properties. For example, one could not substitute a multiple cloning site for a promoter and expect to obtain the same function

or effect, and a reference teaching a multiple cloning site would not anticipate or suggest a promoter. Further, a search for each type of molecule would require the use of different search terms. Finally, Applicant has not provided evidence or admitted that the various species are not patentably distinct. Accordingly, Applicant's arguments are not persuasive.

The requirement is still deemed proper and is therefore made FINAL. However, Applicant is reminded that upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

3. Claims 3-9, 12-14, 17, 22-25, 30-31 and 35, as well molecules not including attB1 sequences, and (regarding claims 10-14) functional or structural sequences other than transcriptional regulatory sequences, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected election, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement with regard to the election of one species of functional or structural sequence encompassed by claims 10-14 in the Reply of June 27, 2002.

Additionally, vectors other than pMAB58, pMAB62, pMAB85, and pMAB86 are withdrawn from consideration (see claim 33 and discussion above).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 33-34 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims require a variety of particular vectors. While the specification provides maps of a variety of these vectors, the specification does not teach, e.g., the complete sequences thereof, or provide sufficient information regarding the structures of these vectors such that one of skill in the art could be expected to prepare them without undue experimentation. Because the sequences of the listed vectors are not known and because it is not clear whether the vectors are publicly available or can be reproducibly isolated from nature without undue experimentation, a suitable deposit for patent purposes is required. Without the publicly available deposit of the above vectors, one of ordinary skill in the art could not be assured of the ability to make and use the claimed invention. Furthermore, in the event that the deposit is/was made after the effective filing date of the application, Applicant must provide a statement to corroborate that the deposited material is the material specifically identified in the application (see MPEP 2406.02).

If Applicants deposit with an International Deposit Authority is/has been made under the Budapest Treaty, the specification should be amended to recite all of the following: that the deposit has been made under the Budapest Treaty, the deposit accession number, the date of the deposit and the name and address of the depository.

For further information concerning deposit practice, Applicants attention is directed to 37 CFR 1.801-1.809 and MPEP 2401-2411.05.

If Applicants deposit with an International Deposit Authority is not/has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(A) During the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(B) All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(C) The deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(D) The deposits were viable at the time of deposit;

and;

(E) The deposits will be replaced if they should ever become non-viable.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 2, 10-11, 15-16, 18-21, 26-29, 32, and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 10-11, 15-16, 18-21, and 36-38 are indefinite over the recitation of the language "an ____ nucleotide sequence as set forth in Figure 9" because this language does not clearly limit the claims to a particular sequence. For example, it is unclear whether the recitation "an attB1 nucleotide sequence as set forth in Figure 9" refers only to the full length sequence designated attB1 in the Figure, or whether, e.g., subsequences of this sequence would also be considered to constitute "an attB1 nucleotide sequence." Clarification is required.

Claims 1, 10-11, 15-16, 18-21, and 36-38 are indefinite over the recitation of the phrase "a polynucleotide complementary thereto, and a mutant, fragment or derivative thereof" in claim 1. Prior to the recitation of this phrase, claim 1 recites a list of several nucleotide sequences, and it is unclear whether the language "polynucleotide complementary thereto" is intended to require a sequence that is a complement of each of the previously recited sequences, of any of these sequences, or of only the sequence recited immediately prior to the recitation (i.e., "an attR2 nucleotide sequence as set forth in Figure 9"). Similarly, it is unclear whether the language "a mutant, fragment or derivative thereof" refers to mutants/fragments/derivatives of each of the previously recited sequences, of any of these sequences, or of only the sequence recited immediately prior to the recitation. Accordingly, it is unclear as to what isolated nucleic acid molecules are encompassed by the claims.

Claim 11 is indefinite because it is unclear as to how or whether the claim is intended to further limit the claims to the extent that the claims are drawn to sequence or sequences of claim 10 other than a transcriptional regulatory sequence. For

example, does claim 11 further limit a molecule comprising a multiple cloning site, and if so, how? This rejection could be overcome by amending the claim such that it actually requires one or more "functional or structural nucleotide sequences" of the type recited in the claims. For example, claim 11 could be amended to recite "wherein said one or more functional or structural nucleotide sequences include one or more transcriptional regulatory sequences, and wherein said one or more transcriptional regulatory sequences is/are selected from one or more promoters, one or more enhancers, and one or more repressors."

Claim 11 is indefinite over the recitation of the limitation "said transcriptional regulatory sequence" because there is insufficient antecedent basis for this limitation in the claims. While claim 10 refers to "one or more transcriptional regulatory sequences," the claim does not recite a particular "transcriptional regulatory sequence."

Claims 15-16, 18 and 37 are indefinite over the recitation of the phrase "comprising the isolated nucleic acid molecule of claim 1 or a portion thereof linked to a target-specific nucleotide sequence useful in amplifying said target nucleotide sequence" in claim 15. First, it is unclear as to whether this recitation refers back to and limits the "primer nucleic acid molecule" or the "target nucleotide sequence." Second, it is unclear whether the recitation "linked to a target-specific nucleotide sequence useful in amplifying said target nucleotide sequence" limits only the previously reciting "portion thereof" or whether this limitation applies to any primer encompassed by the claims.

Claim 16 is indefinite over the recitation of the phrase "the sequence shown in Figure 9." As multiple sequences appear in Figure 9, it is unclear as to which of these sequences would constitute "the sequence" of the claim.

Claims 26-28 and 36 are indefinite over the recitation of the limitation "its core region" in claim 26 because it is unclear as to whether "it" refers to the "isolated nucleic acid molecule," to "one or more *att* recombination sites," or to a particular single *att* recombination site. Clarification is required.

Claims 26-28 and 36 are indefinite over the recitation of the limitation "said recombination site" in claim 26 because there is insufficient antecedent basis for this limitation in the claims. Claim 26 previously refers to "one or more" recombination sites but not to a particular recombination site.

Claim 27 is indefinite over the recitation of the limitations "said mutation" and "the seven basepair overlap region of said core region of said recombination site" because there is insufficient antecedent basis for these limitations in the claims.

Claim 28 is indefinite over the recitation of the limitation "the consensus sequence" because there is insufficient antecedent basis for this limitation in the claims.

Claims 29 and 32 are indefinite over the recitation of the limitation "its core region" in claim 29 because it is unclear as to whether "it" refers to the "isolated nucleic acid molecule," to "one or more mutated *att* recombination sites," or to a particular single mutated *att* recombination site. Clarification is required.

Claims 29 and 32 are indefinite over the recitation of the limitation "said mutated *att* recombination site" because there is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2, 10-11, 15-16, 18-21, 26-29, and 36-38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Life Technologies, Inc. (WO 96/40724 [12/1996]; hereinafter referred to as "LT").

LT teaches a variety of recombination site core regions, including a sequence identified as SEQ ID NO: 6, as well as a "corresponding or complementary DNA or RNA sequence" (see entire reference, particularly pages 29-30). As LT's SEQ ID NO: 6 is the exact complement of the sequence disclose by Applicant in Figure 9 as "attB1," LT discloses an isolated nucleic acid molecule comprising a "an attB1 nucleotide sequence as set forth in Figure 9," as well as the complement thereof. Regarding claims 19-21, LT discloses vectors comprising one, two, or more of their recombination sites; the vectors taught by LT include expression vectors, and LT further teaches host cells comprising their vectors (see, e.g., pages 8, 10-11, 17-18). With respect to claims 10-11, LT teaches inclusion of transcriptional regulatory sequences, including promoters, in their molecules/vectors (see, e.g., page 13). Regarding claims 15-16 and 18, it is an

inherent property of LT's SEQ ID NO: 6 and the complement thereof that these molecules could be used as primers in, e.g., PCR. Accordingly, LT teaches nucleic acid molecules meeting the requirements of the claims. Regarding claims 26-29, LT discloses the introduction of mutations into recombination sites to enhance recombination, and teaches mutations and molecules comprising said mutations meeting the requirements of the claims (see pages 27-30). Regarding claims 36-38, LT discloses kits comprising vectors including their recombination site sequences (see, e.g., pages 7-8 and claims 7-9).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Diana B. Johannsen
Patent Examiner
February 9, 2004